# APPENDIX A. SUBMISSION SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**A. Name, Address, Phone and Fax Number of the Applicant**

Guidant Cardiac & Vascular Surgery (C&VS)
1360 O'Brien Drive
Menlo Park, CA 94025

Telephone: (650) 470-6200
Fax: (650) 470-6320

**B. Contact Person**

Jacqueline J. Jackson
Manager, Regulatory Affairs

**C. Date Prepared**

8 November 2000

**D. Device Name**

Trade Name: Ancure® Iliac Balloon Catheter
Classification Name: Balloon Dilatation Catheter, Class II

**E. Device Description**

The Ancure Iliac Balloon Catheter (Ancure IBC) is a balloon dilatation catheter made up of a balloon at the distal end, a dual-lumen catheter shaft, and a two-port extension manifold at the proximal end. One lumen is used for balloon inflation and deflation. The second lumen accommodates a guidewire with a recommended diameter of 0.035" (0.89 mm). The Ancure IBC is manufactured in various balloon diameters, from 9.5 mm – 14.5 mm, all with a nominal balloon length of 3 cm. Radiopaque markers on the balloon shaft are used to ensure proper positioning prior to balloon inflation.

The Ancure IBC is provided sterile to the end user. It is disposable, with a useable life of one procedure.

**F. Intended Use**

The Ancure IBC is designed to secure attachment systems in the iliac arteries and/or to expand vascular prosthesis limbs.

## G. Substantial Equivalence

The Ancure IBC is substantially equivalent to the VANTAGE Peripheral Dilatation Catheter (510(k) K965183) and the B Braun Z-Med™ II Peripheral Balloon Dilatation Catheter (510(k) K951248). The Ancure IBC is similar to the Vantage and B Braun Z-Med II catheters with respect to the design, materials, and performance. The maximum operating pressure recommended for the Ancure IBC is 2 ATM while the Vantage catheter is cleared for use at a higher pressure of 13 ATM and the Z-Med balloons operate at varying pressures for the diameter of balloon desired.

## H. Device Testing Results and Conclusion

### Bench Test Results

| Bench Test | Results |
|---|---|
| Manifold Joint Testing | Pass |
| Extensions Joint Testing | Pass |
| Balloon Shaft Butt Joint Testing | Pass |
| Radiopaque Marker Bond Joint Testing | Pass |
| Balloon Leak Testing | Pass |
| Balloon Burst Testing | Pass |
| Balloon Inflation/Deflation Rate Testing | Pass |
| Catheter Shaft Burst Testing | Pass |
| Functional Testing (Flow Lab Modeling) | Pass |
| Hook Penetration | Pass |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

GUIDANT Corporation
Cardiac & Vascular Surgery Group
c/o Ms. Jacqueline J. Jackson
Regulatory Affairs Manager
1525 O'Brien Drive
Menlo Park, CA 94025

Re: K003495
Trade Name: Ancure® Iliac Balloon Catheter
Regulatory Class: II (two)
Product Code: DQY and LIT
Dated: November 09, 2000
Received: November 13, 2000

Dear Ms. Jackson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# APPENDIX B. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003495

Device Name: Ancure ™ Iliac Balloon Catheter

Indications for Use: The Ancure Iliac Balloon Catheter is designed to secure the attachment systems in the iliac arteries and/or to expand vascular prosthesis limbs.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K003495